

DOCKETED

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
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PCT

WRITTEN OPINION

(PCT Rule 66)

Applicant's or agent's file reference		Date of Mailing (day/month/year)
PCA-1865AU		30 AUG 2004
International application No.	International filing date (day/month/year)	Priority date (day/month/year)
PCT/US03/21756	11 July 2003 (11.07.2003)	16 July 2002 (16.07.2002)
International Patent Classification (IPC) or both national classification and IPC		
IPC(7): A61M 29/00 and US Cl.: 604/96.01, 104, 908, 912, 915		
Applicant		
APPLIED MEDICAL RESOURCES CORPORATION		

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2 (a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension. See rule 66.2(d).~~

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 *bis*.
For an informal communication with the examiner, see Rule 66.6

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 16 November 2004 (16.11.2004)

Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer <i>Sharon N. Greene for</i> John Calvert Telephone No. 703-306-0858
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I. Basis of the opinion

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed
- ☒ the description:
pages 1-9 _____, as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____.
- ☒ the claims:
pages 10-20 _____, as originally filed
pages NONE _____, as amended (together with any statement) under Article 19
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____.
- ☒ the drawings:
pages 1-7 _____, as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____.
- ☐ the sequence listing part of the description:
pages NONE _____, as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE _____
- ☐ the claims, Nos. NONE _____
- ☐ the drawings, sheets/fig NONE _____

5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims <u>11-14</u>	YES
	Claims <u>1-5, 7-9, 15 and 16</u>	NO
Inventive Step (IS)	Claims <u>11-14</u>	YES
	Claims <u>1-10 and 15-20</u>	NO
Industrial Applicability (IA)	Claims <u>1-20</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Please See Continuation Sheet

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

TIME LIMIT:

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.

V. 2. Citations and Explanations:

Claims 1-5 and 7-9 lack novelty under PCT Article 33(2) as being anticipated by Hart et al. (US 6,183,492 B1).

Regarding claim 1, Hart et al. teach a drainage catheter (200) adapted to drain fluid from a body cavity through a body conduit, comprising an elongate tube (30) having a proximal and distal end, and being sized and configured for insertion into the body cavity; an expandable retention member (20) disposed at the distal end of the elongate tube (30) and being adapted for movement between a low-profile state facilitating insertion of the catheter (200) into a body cavity, and an expanded high-profile state facilitating retention of the distal end of the catheter (200) in the body cavity; and a stylet (300) removably insertable into the elongate tube (30) to facilitate insertion and placement of the catheter (200) in the body cavity (figures 9, 10 and 17)(col. 5, lines 47-57).

Regarding claims 2 and 3, Hart et al. teach that the retention member (400) is constructed of woven fabric or mesh (col. 5, lines 47-57).

Regarding claims 4, 5, 7 and 8, see figures 9 and 10.

Regarding claim 9, see element 100.

Claims 6 and 10 lack an inventive step under PCT Article 33(3) as being obvious over Hart et al.

Regarding claim 6, it is well known in the medical arts to use plastic or metal stylets and the selection of such materials does not patentably distinguish the invention over the reference.

Regarding claim 10, snap fit connections are one of many well known mechanical expedients, such as lock-fit, screw fit, etc., that are well known in the art for connecting subcomponents.

Claims 15 and 16 lack novelty under PCT Article 33(2) as being anticipated by Mickley et al. (US 6,264,630 B1).

Mickey et al. teach a drainage catheter comprising an elongate tube (22), an expandable retention member (24) disposed at the distal end of the tube adapted to move between expanded and non-expanded states to facilitate retention and insertion respectively, and an energy storing member (106, 112) at the distal end of the tube to assist the retention member in collapsing.

Regarding claim 16, Mickley et al. teach metallic wires (col. 10, lines 53-66).

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Claims 17-20 lack an inventive step under PCT Article 33(3) as being obvious over Mickley et al.

Mickley et al. teach the claimed invention except for the use of specific types of wire. The claimed materials are commonly used in the relevant art to provide tensioning or spring energy and do not patentably distinguish the invention over the art.

Claims 11-14 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the claimed one-way plug structure, or a ratcheting member.

Claims 1-20 meet the criteria set out in PCT Article 33(4), and thus meet industrial applicability because the subject matter claimed can be made or used in industry.

----- NEW CITATIONS -----